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C. R. Bard, Inc. and
Bard Peripheral Vascular, Inc.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF ARIZONA

IN RE: Bard IVC Filters Products Liability MDL NO. 15-02641-PHX-DGC
Litigation

This Document Relates to:

GARY LEIGH PIAZZA,

Plaintiff,

v.

C. R. BARD, INC. and BARD
PERIPHERAL VASCULAR INC.,

Defendants.

Case No. CV-15-02656-PHX-DGC

**DEFENDANTS C. R. BARD, INC. AND
BARD PERIPHERAL VASCULAR,
INC.'S ANSWER AND AFFIRMATIVE
DEFENSES AND DEMAND FOR
TRIAL BY JURY**

Defendants C. R. Bard, Inc. (“Bard”) and Bard Peripheral Vascular, Inc. (“BPV”) (Bard and BPV are collectively “Defendants”) answer the Complaint (“Plaintiff’s Complaint”) of Plaintiff Gary Leigh Piazza (“Plaintiff”) as follows:

INTRODUCTORY ALLEGATIONS¹

1. Defendants admit that Plaintiff has brought this civil action for damages but deny that Plaintiff has suffered any personal injuries caused by Defendants, deny that Defendants are liable to Plaintiff, and deny that Plaintiff is entitled to any damages from Defendants. Defendants deny any remaining allegations contained in Paragraph 1 of Plaintiff’s Complaint.

2. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding the trade name of any inferior vena cava filter implanted in Plaintiff. Defendants admit that Plaintiff has brought this civil action for damages but deny that Plaintiff has suffered any personal injuries caused by Defendants, deny that Defendants are liable to Plaintiff, and deny that Plaintiff is entitled to any damages from Defendants. Defendants deny any remaining allegations contained in Paragraph 2 of Plaintiff’s Complaint.

3. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding the trade name of any inferior vena cava filter implanted in Plaintiff and, therefore, deny them. Defendants admit that Plaintiff has brought this civil action for damages but deny that Plaintiff has suffered any personal injuries caused by Defendants, deny that Defendants are liable to Plaintiff, and deny that Plaintiff is entitled to any damages from Defendants. Defendants deny any remaining allegations contained in Paragraph 3 of Plaintiff’s Complaint.

¹ The portion of Plaintiff’s Complaint subtitled “Table of Contents” and contained on pgs i. and ii. do not contain allegations directed at Defendants and, as a result, require no response from Defendants. To the extent this section does make allegations against Defendants, any such allegations are denied.

1 12. Defendants admit that Bard owns a facility where vena cava filters are
2 manufactured. Defendants further admit that BPV designs, sells, markets, and distributes
3 inferior vena cava filters. Defendants also admit that both Bard and BPV are authorized to do
4 business, and do business, in the State of New York. Defendants deny any remaining
5 allegations contained in Paragraph 12 of Plaintiff's Complaint.

6 **JURISDICTION AND VENUE**

7 13. Regarding Paragraph 13 of Plaintiff's Complaint, Defendants do not contest
8 that the injuries and damages alleged within Plaintiff's Complaint exceed the jurisdictional
9 limit of this Court. However, Defendants deny that they are liable to Plaintiff for any amount
10 whatsoever and deny that Plaintiff has suffered any damages whatsoever. Defendants do not
11 dispute that, based on the facts as alleged by Plaintiff, which have not been, and could not
12 have been confirmed by Defendants, jurisdiction appears to be proper in the United States
13 District Court for the Western District of New York.

14 14. Regarding Paragraph 14 of Plaintiff's Complaint, Defendants do not dispute
15 that, based on the facts as alleged by Plaintiff, which have not been and could not have been
16 confirmed by Defendants, venue appears to be proper in the United States District Court for
17 the Western District of New York.

18 **GENERAL FACTUAL ALLEGATIONS**

19 15. Defendants lack knowledge or information sufficient to form a belief as to the
20 truth of the allegation regarding the time frame when inferior vena cava filters were first
21 introduced on the market or the identity of manufacturers of inferior vena cava filters.
22 Defendants deny any remaining allegations of Paragraph 15 of Plaintiff's Complaint.

23 16. Defendants admit that inferior vena cava filters are intended to prevent injury or
24 death resulting from venous thrombosis and pulmonary embolism. Defendants further admit
25 that inferior vena cava filters may be designed for permanent placement, temporary
26 placement, or both. Defendants deny any remaining allegations of Paragraph 16 of Plaintiff's
27 Complaint.

1 17. Defendants admit that the inferior vena cava is a large vein that receives blood
2 from the lower regions of the body and delivers it to the right atrium of the heart. Defendants
3 further admit that deep vein thrombosis and pulmonary emboli present dangerous risks to
4 human health, including sometimes death. Defendants deny any remaining allegations of
5 Paragraph 17 of Plaintiff's Complaint.

6 18. Defendants admit that patients at a high risk for developing deep vein
7 thrombosis and pulmonary embolism are frequently treated with anticoagulation therapy,
8 including but not limited to the medications listed in Paragraph 18 of Plaintiff's Complaint.
9 Defendants further admit that inferior vena cava filters may also be used to treat patients who
10 are at a high risk for developing deep vein thrombosis and pulmonary embolism. Defendants
11 lack knowledge or information sufficient to form a belief as to the truth of any remaining
12 allegations contained in Paragraph 18 of Plaintiff's Complaint and, on that basis, deny them.

13 19. Defendants are without knowledge or information sufficient to form a belief as
14 to the allegations contained in Paragraph 19 of Plaintiff's Complaint and, therefore, deny
15 them.

16 20. Defendants admit that the Recovery® Filter was cleared by the FDA for
17 retrievable placement on July 25, 2003, pursuant to applications submitted under
18 Section 510(k) of the Food, Drug and Cosmetic Act. Defendants deny any remaining
19 allegations contained in Paragraph 20 of Plaintiff's Complaint.

20 21. The allegations contained in Paragraph 21 of Plaintiff's Complaint are legal
21 conclusions, to which no response is required. To the extent a response is required,
22 Defendants deny those allegations.

23 22. Defendants admit that Bard has distributed the Simon Nitinol Filter in the
24 United States since at least 1992. Defendants admit that, as part of their continuing efforts to
25 constantly evaluate the medical devices they sell, in conjunction with the ever-changing state-
26 of-the-art, they are continually striving to improve the life-saving performance of those
27 devices. The Recovery® Filter was developed in furtherance of those efforts. Defendants
28

1 further admit that the Recovery® Filter was cleared by the FDA for optional use as a
2 retrievable inferior vena cava filter. Defendants deny any remaining allegations contained in
3 Paragraph 22 of Plaintiff's Complaint, including any allegations contained in Footnote 1.

4 23. Defendants deny the allegations contained in Paragraph 23 of Plaintiff's
5 Complaint.

6 24. Defendants deny the allegations contained in Paragraph 24 of Plaintiff's
7 Complaint.

8 25. Defendants deny the allegations contained in Paragraph 25 of Plaintiff's
9 Complaint.

10 26. Defendants admit that the Recovery® Filter was cleared by the FDA for
11 permanent placement on November 27, 2002, pursuant to an application submitted under
12 Section 510(k) of the Food, Drug and Cosmetic Act. The allegations contained in Footnote 2
13 regarding the 510(k) process are conclusions of law, to which no response is required. To the
14 extent a response is required, Defendants deny those allegations. Defendants deny any
15 remaining allegations contained in Paragraph 26 of Plaintiff's Complaint, including any
16 additional allegations in Footnote 2.

17 27. Defendants admit that the Recovery® Filter was cleared by the FDA for
18 retrievable placement on July 25, 2003, pursuant to applications submitted under
19 Section 510(k) of the Food, Drug and Cosmetic Act. Defendants deny any remaining
20 allegations contained in Paragraph 27 of Plaintiff's Complaint.

21 28. Defendants deny the allegations contained in Paragraph 28 of Plaintiff's
22 Complaint.

23 29. Defendants deny the allegations contained in Paragraph 29 of Plaintiff's
24 Complaint.

25 30. Defendants admit that the Recovery® Filter consists of twelve, shape-memory
26 Nitinol wires emanating from a central Nitinol sleeve. Defendants further admit that the
27 twelve wires form two levels of filtration for emboli: the legs provide the lower level of
28

1 filtration, and the arms provide the upper level of filtration. Defendants deny any remaining
2 allegations contained in Paragraph 30 of Plaintiff's Complaint.

3 31. Defendants admit that the Recovery® Filter was designed to be inserted
4 endovascularly. Defendants further admit that the Recovery® Filter is designed to be
5 delivered via an introducer sheath, which is included in the delivery system for the device.
6 Defendants deny any remaining allegations of Paragraph 31 of Plaintiff's Complaint.

7 32. Defendants admit that, as part of their continuing efforts to constantly evaluate
8 the medical devices they sell, in conjunction with the ever-changing state-of-the-art, they are
9 continually striving to improve the life-saving performance of those devices. The Recovery®
10 Filter was developed in furtherance of those efforts. Defendants deny the remaining
11 allegations contained in Paragraph 32 of Plaintiff's Complaint, including all sub-parts thereof.

12 33. Defendants deny the allegations contained in Paragraph 33 of Plaintiff's
13 Complaint.

14 34. Defendants deny the allegations contained in Paragraph 34 of Plaintiff's
15 Complaint.

16 35. Defendants deny the allegations contained in Paragraph 35 of Plaintiff's
17 Complaint, including all sub-parts thereof.

18 36. Defendants deny the allegations contained in Paragraph 36 of Plaintiff's
19 Complaint, including any allegations contained in Footnote 3.

20 37. Defendants deny the allegations contained in Paragraph 37 of Plaintiff's
21 Complaint.

22 38. Defendants deny the allegations contained in Paragraph 38 of Plaintiff's
23 Complaint, including all sub-parts thereof.

24 39. Defendants deny the allegations contained in Paragraph 39 of Plaintiff's
25 Complaint.

26 40. Defendants deny the allegations contained in Paragraph 40 of Plaintiff's
27 Complaint.

1 41. Defendants deny the allegations contained in Paragraph 41 of Plaintiff's
2 Complaint. By way of further response, Defendants admit that there are various well-
3 documented complications that may occur as a result of the fracture, perforation, and/or
4 migration of any inferior vena cava filter. Defendants further admit that it is well documented
5 that many instances of filter fracture and/or migration result in no complications whatsoever
6 but, rather, are completely asymptomatic. Bard further states that there are incidents related to
7 the occurrence of known complications associated with every manufacturer of inferior vena
8 cava filters. Defendants deny the remaining allegations of Paragraph 41 of Plaintiff's
9 Complaint, including all sub-parts thereof.

10 42. Defendants deny the allegations contained in Paragraph 42 of Plaintiff's
11 Complaint.

12 43. Defendants deny the allegations contained in Paragraph 43 of Plaintiff's
13 Complaint, including all subparts thereof.

14 44. Defendants deny the allegations contained in Paragraph 44 of Plaintiff's
15 Complaint.

16 45. Defendants deny the allegations contained in Paragraph 45 of Plaintiff's
17 Complaint.

18 46. Defendants deny the allegations contained in Paragraph 46 of Plaintiff's
19 Complaint as stated. By way of further answer, Defendants state that, as part of their
20 continuing efforts to constantly evaluate the medical devices they sell, in conjunction with the
21 ever-changing state-of-the-art, they are continually striving to improve the life-saving
22 performance of those devices.

23 47. Defendants deny the allegations contained in Paragraph 47 of Plaintiff's
24 Complaint.

25 48. Defendants deny the allegations contained in Paragraph 48 of Plaintiff's
26 Complaint.

1 49. Defendants deny the allegations contained in Paragraph 49 of Plaintiff's
2 Complaint.

3 50. Defendants deny the allegations contained in Paragraph 50 of Plaintiff's
4 Complaint.

5 51. Defendants deny the allegations contained in Paragraph 51 of Plaintiff's
6 Complaint.

7 52. Defendants deny the allegations contained in Paragraph 52 of Plaintiff's
8 Complaint.

9 53. Defendants deny the allegations contained in Paragraph 53 of Plaintiff's
10 Complaint.

11 54. Defendants deny the allegations contained in Paragraph 54 of Plaintiff's
12 Complaint.

13 55. Defendants deny the allegations contained in Paragraph 55 of Plaintiff's
14 Complaint.

15 56. Defendants deny the allegations contained in Paragraph 56 of Plaintiff's
16 Complaint.

17 57. Defendants deny the allegations contained in Paragraph 57 of Plaintiff's
18 Complaint.

19 58. Defendants deny the allegations contained in Paragraph 58 of Plaintiff's
20 Complaint.

21 59. Defendants deny the allegations contained in Paragraph 59 of Plaintiff's
22 Complaint, including all sub-parts thereof.

23 60. Defendants deny the allegations contained in Paragraph 60 of Plaintiff's
24 Complaint. Defendants deny that the Recovery® Filter is unreasonably dangerous or
25 defective in any manner. By way of further answer, Defendants state that, as part of their
26 continuing efforts to constantly evaluate the medical devices they sell, in conjunction with the
27 ever-changing state-of-the-art, they are continually striving to improve the life-saving
28

1 performance of those devices. The G2® Filter was developed in furtherance of those efforts.
2 Defendants deny any remaining allegations contained in Paragraph 60 of Plaintiff's
3 Complaint.

4 61. Defendants deny the allegations contained in Paragraph 61 of Plaintiff's
5 Complaint.

6 62. Defendants deny the allegations contained in Paragraph 62 of Plaintiff's
7 Complaint.

8 63. Defendants deny the allegations contained in Paragraph 63 of Plaintiff's
9 Complaint.

10 64. Defendants deny the allegations contained in Paragraph 64 of Plaintiff's
11 Complaint.

12 65. Defendants admit the G2® Filter System was cleared by the United States Food
13 and Drug Administration pursuant to an application submitted under Section 510(k) of the
14 Food, Drug and Cosmetic Act in 2005. Defendants deny any remaining allegations contained
15 in Paragraph 65 of Plaintiff's Complaint.

16 66. Defendants are without knowledge or information sufficient to form a belief as
17 to the truth of the allegations contained in Paragraph 66 of Plaintiff's Complaint. By way of
18 further answer, the rendering contained in Paragraph 66 is similar in appearance to a G2®
19 Filter.

20 67. Defendants admit the G2® Filter System was cleared by the United States Food
21 and Drug Administration for both permanent and retrievable use pursuant to an application
22 submitted under Section 510(k) of the Food, Drug and Cosmetic Act. Defendants further
23 admit that the G2® Filter was originally cleared by the FDA for permanent use and was
24 subsequently cleared in 2008 by the FDA for optional use as a retrievable inferior vena cava
25 filter. Defendants deny any remaining allegations contained in Paragraph 67 of Plaintiff's
26 Complaint.

1 68. Defendants deny the allegations contained in Paragraph 68 of Plaintiff's
2 Complaint.

3 69. Defendants deny the allegations contained in Paragraph 69 of Plaintiff's
4 Complaint.

5 70. Defendants deny the allegations contained in Paragraph 70 of Plaintiff's
6 Complaint.

7 71. Defendants deny the allegations contained in Paragraph 71 of Plaintiff's
8 Complaint.

9 72. Defendants deny the allegations contained in Paragraph 72 of Plaintiff's
10 Complaint.

11 73. Defendants deny the allegations contained in Paragraph 73 of Plaintiff's
12 Complaint.

13 74. Defendants deny the allegations contained in Paragraph 74 of Plaintiff's
14 Complaint.

15 75. Defendants deny the allegations contained in Paragraph 75 of Plaintiff's
16 Complaint.

17 76. Defendants deny the allegations contained in Paragraph 76 of Plaintiff's
18 Complaint, including all sub-parts thereof.

19 77. Defendants deny the allegations contained in Paragraph 77 of Plaintiff's
20 Complaint, including all sub-parts thereof.

21 78. Defendants deny the allegations contained in Paragraph 78 of Plaintiff's
22 Complaint.

23 79. Defendants admit that Bard received a warning letter from the FDA's Los
24 Angeles District Office dated July 13, 2015. Defendants deny the remaining allegations of
25 Paragraph 79 of the Complaint as stated.

26 80. Defendants deny the allegations contained in Paragraph 80 of Plaintiff's
27 Complaint.

1 81. Defendants deny the allegations contained in Paragraph 81 of Plaintiff's
2 Complaint.

3 82. Defendants deny the allegations contained in Paragraph 82 of Plaintiff's
4 Complaint.

5 83. Defendants deny the allegations contained in Paragraph 83 of Plaintiff's
6 Complaint.

7 84. Defendants are without knowledge or information sufficient to form a belief as
8 to the truth of the allegations contained in Paragraph 84 of Plaintiff's Complaint and,
9 therefore, deny them.

10 85. Defendants are without knowledge or information sufficient to form a belief as
11 to the truth of the allegations contained in Paragraph 85 of Plaintiff's Complaint and,
12 therefore, deny them.

13 86. Defendants are without knowledge or information sufficient to form a belief as
14 to the truth of the allegations contained in Paragraph 86 of Plaintiff's Complaint and,
15 therefore, deny them.

16 87. Defendants are without knowledge or information sufficient to form a belief as
17 to the truth of the allegations contained in Paragraph 87 of Plaintiff's Complaint and,
18 therefore, deny them.

19 88. Defendants are without knowledge or information sufficient to form a belief as
20 to the truth of the allegations contained in Paragraph 88 of Plaintiff's Complaint and,
21 therefore, deny them.

22 89. Defendants are without knowledge or information sufficient to form a belief as
23 to the truth of the allegations contained in Paragraph 89 of Plaintiff's Complaint and,
24 therefore, deny them.

25 90. Defendants deny the allegations contained in Paragraph 90 of Plaintiff's
26 Complaint.

99. Defendants deny the allegations contained in Paragraph 99 of Plaintiff's Complaint.

100. Defendants deny the allegations contained in Paragraph 100 of Plaintiff's Complaint, including all sub-parts thereof.

101. Defendants deny the allegations contained in Paragraph 101 of Plaintiff's Complaint.

102. Defendants deny the allegations contained in Paragraph 102 of Plaintiff's Complaint.

103. Defendants deny the allegations contained in Paragraph 103 of Plaintiff's Complaint, including all sub-parts thereof.

104. Defendants deny the allegations contained in Paragraph 104 of Plaintiff's Complaint.

105. Defendants deny the allegations contained in Paragraph 105 of Plaintiff's Complaint.

SECOND CAUSE OF ACTION

NEGLIGENT FAILURE TO WARN

106. Defendants incorporate by reference their responses to Paragraphs 1-105 of Plaintiff's Complaint as if fully set forth herein.

107. Defendants admit that Bard owns a facility where vena cava filters are manufactured. Defendants further admit that BPV designs, sells, markets, and distributes inferior vena cava filters. Defendants deny any remaining allegations contained in Paragraph 107 of the Complaint.

108. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding the trade name of any inferior vena cava filter implanted in Plaintiff and, on that basis, deny them. By way of further response, Defendants admit that Bard owns a facility where vena cava filters are manufactured. Defendants further

1 admit that BPV designs, sells, markets, and distributes inferior vena cava filters. Defendants
2 deny any remaining allegations contained in Paragraph 108 of Plaintiff's Complaint.

3 109. The allegations contained in Paragraph 109 regarding Defendants' duty are
4 legal conclusions, and no answer is required. To the extent a response is required, Defendants
5 deny the allegations. Defendants deny any remaining allegations contained in Paragraph 109
6 of the Complaint.

7 110. Defendants deny the allegations contained in Paragraph 110 of Plaintiff's
8 Complaint.

9 111. Defendants deny the allegations contained in Paragraph 111 of Plaintiff's
10 Complaint, including all sub-parts thereof.

11 112. Defendants deny the allegations contained in Paragraph 112 of Plaintiff's
12 Complaint.

13 113. Defendants deny the allegations contained in Paragraph 113 of Plaintiff's
14 Complaint.

15 114. Defendants deny the allegations contained in Paragraph 114 of Plaintiff's
16 Complaint.

17 115. Defendants deny the allegations contained in Paragraph 115 of Plaintiff's
18 Complaint.

19 116. Defendants deny the allegations contained in Paragraph 116 of Plaintiff's
20 Complaint.

21 **THIRD CAUSE OF ACTION**

22 **STRICT LIABILITY – FAILURE TO WARN**

23 117. Defendants incorporate by reference their responses to Paragraphs 1-116 of
24 Plaintiff's Complaint as if fully set forth herein.

25 118. Defendants are without knowledge or information sufficient to form a belief as
26 to the truth of the allegations regarding the trade name of any inferior vena cava filter
27 implanted in Plaintiff and, on that basis, deny them. By way of further response, Defendants
28

1 admit that Bard owns a facility where vena cava filters are manufactured. Defendants further
2 admit that BPV designs, sells, markets, and distributes inferior vena cava filters. Defendants
3 deny any remaining allegations contained in Paragraph 118 of Plaintiff's Complaint.

4 119. Defendants deny the allegations contained in Paragraph 119 of Plaintiff's
5 Complaint.

6 120. The allegations contained in Paragraph 120 of Plaintiff's Complaint are legal
7 conclusions, to which no response is required. To the extent a response is required,
8 Defendants deny those allegations.

9 121. The allegations contained in Paragraph 121 of Plaintiff's Complaint are legal
10 conclusions, to which no response is required. To the extent a response is required,
11 Defendants deny those allegations.

12 122. Defendants deny the allegations contained in Paragraph 122 of Plaintiff's
13 Complaint.

14 123. Defendants deny the allegations contained in Paragraph 123 of Plaintiff's
15 Complaint.

16 124. Defendants deny the allegations contained in Paragraph 124 of Plaintiff's
17 Complaint.

18 125. Defendants deny the allegations contained in Paragraph 125 of Plaintiff's
19 Complaint.

20 126. Defendants deny the allegations contained in Paragraph 126 of Plaintiff's
21 Complaint.

22 127. Defendants deny the allegations contained in Paragraph 127 of Plaintiff's
23 Complaint.

24 128. Defendants deny the allegations contained in Paragraph 128 of Plaintiff's
25 Complaint.

FOURTH CAUSE OF ACTION

STRICT LIABILITY – DESIGN DEFECT

129. Defendants incorporate by reference their responses to Paragraphs 1-128 of Plaintiff's Complaint as if fully set forth herein.

130. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding the trade name of any inferior vena cava filter implanted in Plaintiff and, on that basis, deny them. By way of further response, Defendants admit that Bard owns a facility where vena cava filters are manufactured. Defendants further admit that BPV designs, sells, markets, and distributes inferior vena cava filters. Defendants deny any remaining allegations contained in Paragraph 130 of Plaintiff's Complaint.

131. Defendants deny the allegations contained in Paragraph 131 of Plaintiff's Complaint.

132. Defendants deny the allegations contained in Paragraph 132 of Plaintiff's Complaint.

133. Defendants deny the allegations contained in Paragraph 133 of Plaintiff's Complaint.

134. Defendants deny the allegations contained in Paragraph 134 of Plaintiff's Complaint.

135. Defendants deny the allegations contained in Paragraph 135 of Plaintiff's Complaint.

136. Defendants deny the allegations contained in Paragraph 136 of Plaintiff's Complaint.

FIFTH CAUSE OF ACTION

STRICT LIABILITY – MANUFACTURING DEFECT

137. Defendants incorporate by reference their responses to Paragraphs 1-136 of Plaintiff's Complaint as if fully set forth herein.

1 147. Defendants deny the allegations contained in Paragraph 147 of Plaintiff's
2 Complaint.

3 **SEVENTH CAUSE OF ACTION**

4 **BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY AND FITNESS**

5 148. Defendants incorporate by reference their responses to Paragraphs 1-147 of
6 Plaintiff's Complaint as if fully set forth herein.

7 149. Defendants admit that Bard owns a facility where vena cava filters are
8 manufactured. Defendants further admit that BPV designs, sells, markets, and distributes
9 inferior vena cava filters. Defendants deny any remaining allegations contained in
10 Paragraph 149 of Plaintiff's Complaint.

11 150. Defendants deny the allegations contained in Paragraph 150 of Plaintiff's
12 Complaint.

13 151. Defendants deny the allegations contained in Paragraph 151 of Plaintiff's
14 Complaint.

15 152. Defendants deny the allegations contained in Paragraph 152 of Plaintiff's
16 Complaint.

17 153. Defendants deny the allegations contained in Paragraph 153 of Plaintiff's
18 Complaint.

19 154. Defendants deny the allegations contained in Paragraph 154 of Plaintiff's
20 Complaint, including all sub-parts thereof.

21 155. Defendants deny the allegations contained in Paragraph 155 of Plaintiff's
22 Complaint.

23 156. Defendants deny the allegations contained in Paragraph 156 of Plaintiff's
24 Complaint.

25 157. Defendants deny the allegations contained in Paragraph 157 of Plaintiff's
26 Complaint.

1 158. Defendants deny the allegations contained in Paragraph 158 of Plaintiff's
2 Complaint.

3 **EIGHTH CAUSE OF ACTION**

4 **BREACH OF IMPLIED WARRANTY OF FITNESS FOR PARTICULAR PURPOSE**

5 159. Defendants incorporate by reference their responses to Paragraphs 1-158 of
6 Plaintiff's Complaint as if fully set forth herein.

7 160. Defendants admit that Bard owns a facility where vena cava filters are
8 manufactured. Defendants further admit that BPV designs, sells, markets, and distributes
9 inferior vena cava filters. Defendants deny any remaining allegations contained in
10 Paragraph 160 of Plaintiff's Complaint.

11 161. Defendants deny the allegations contained in Paragraph 161 of Plaintiff's
12 Complaint.

13 162. Defendants deny the allegations contained in Paragraph 162 of Plaintiff's
14 Complaint.

15 163. Defendants deny the allegations contained in Paragraph 163 of Plaintiff's
16 Complaint.

17 164. Defendants deny the allegations contained in Paragraph 164 of Plaintiff's
18 Complaint.

19 165. Defendants deny the allegations contained in Paragraph 165 of Plaintiff's
20 Complaint, including all sub-parts thereof.

21 166. Defendants deny the allegations contained in Paragraph 166 of Plaintiff's
22 Complaint.

23 167. Defendants deny the allegations contained in Paragraph 167 of Plaintiff's
24 Complaint.

25 168. Defendants deny the allegations contained in Paragraph 168 of Plaintiff's
26 Complaint.

1 169. Defendants deny the allegations contained in Paragraph 169 of Plaintiff's
2 Complaint.

3 **NINTH CAUSE OF ACTION**

4 **FRAUDULENT CONCEALMENT**

5 170. Defendants incorporate by reference their responses to Paragraphs 1-169 of
6 Plaintiff's Complaint as if fully set forth herein.

7 171. The allegations contained in Paragraph 171 of Plaintiff's Complaint are legal
8 conclusions, to which no response is required. To the extent a response is required,
9 Defendants deny those allegations.

10 172. Defendants deny the allegations contained in Paragraph 172 of Plaintiff's
11 Complaint.

12 173. Defendants deny the allegations contained in Paragraph 173 of Plaintiff's
13 Complaint.

14 174. Defendants deny the allegations contained in Paragraph 174 of Plaintiff's
15 Complaint.

16 175. Defendants deny the allegations contained in Paragraph 175 of Plaintiff's
17 Complaint.

18 176. Defendants deny the allegations contained in Paragraph 176 of Plaintiff's
19 Complaint.

20 177. Defendants deny the allegations contained in Paragraph 177 of Plaintiff's
21 Complaint.

22 178. Defendants deny the allegations contained in Paragraph 178 of Plaintiff's
23 Complaint.

24 **TENTH CAUSE OF ACTION**

25 **NEGLIGENT MISREPRESENTATION**

26 179. Defendants incorporate by reference their responses to Paragraphs 1-178 of
27 Plaintiff's Complaint as if fully set forth herein.

1 180. Defendants deny the allegations contained in Paragraph 180 of Plaintiff's
2 Complaint, including all sub-parts thereof.

3 181. Defendants deny the allegations contained in Paragraph 181 of Plaintiff's
4 Complaint.

5 182. Defendants deny the allegations contained in Paragraph 182 of Plaintiff's
6 Complaint.

7 183. Defendants deny the allegations contained in Paragraph 183 of Plaintiff's
8 Complaint.

9 184. Defendants deny the allegations contained in Paragraph 184 of Plaintiff's
10 Complaint.

11 185. Defendants deny the allegations contained in Paragraph 185 of Plaintiff's
12 Complaint.

13 186. The allegations contained in Paragraph 186 of Plaintiff's Complaint are legal
14 conclusions, to which no response is required. To the extent a response is required,
15 Defendants deny those allegations.

16 187. Defendants deny the allegations contained in Paragraph 187 of Plaintiff's
17 Complaint.

18 188. Defendants deny the allegations contained in Paragraph 188 of Plaintiff's
19 Complaint.

20 189. Defendants deny the allegations contained in Paragraph 189 of Plaintiff's
21 Complaint.

22 190. Defendants deny the allegations contained in Paragraph 190 of Plaintiff's
23 Complaint.

24 **ELEVENTH CAUSE OF ACTION**

25 **FRAUDULENT MISREPRESENTATION**

26 191. Defendants incorporate by reference their responses to Paragraphs 1-190 of
27 Plaintiff's Complaint as if fully set forth herein.
28

1 192. Defendants deny the allegations contained in Paragraph 192 of Plaintiff's
2 Complaint.

3 193. Defendants deny the allegations contained in Paragraph 193 of Plaintiff's
4 Complaint, including all sub-parts thereof.

5 194. Defendants deny the allegations contained in Paragraph 194 of Plaintiff's
6 Complaint.

7 195. Defendants deny the allegations contained in Paragraph 195 of Plaintiff's
8 Complaint.

9 196. Defendants deny the allegations contained in Paragraph 196 of Plaintiff's
10 Complaint.

11 197. Defendants deny the allegations contained in Paragraph 197 of Plaintiff's
12 Complaint.

13 198. Defendants deny the allegations contained in Paragraph 198 of Plaintiff's
14 Complaint.

15 199. Defendants deny the allegations contained in Paragraph 199 of Plaintiff's
16 Complaint.

17 200. Defendants deny the allegations contained in Paragraph 200 of Plaintiff's
18 Complaint.

19 201. Defendants deny the allegations contained in Paragraph 201 of Plaintiff's
20 Complaint.

21 202. Defendants deny the allegations contained in Paragraph 202 of Plaintiff's
22 Complaint.

23 **ELEVENTH CAUSE OF ACTION**

24 **PUNITIVE DAMAGES ALLEGATIONS**

25 203. Defendants incorporate by reference their responses to Paragraphs 1-202 of
26 Plaintiff's Complaint as if fully set forth herein.

204. Defendants deny the allegations contained in Paragraph 204 of Plaintiff's Complaint.

205. Defendants deny the allegations contained in Paragraph 205 of Plaintiff's Complaint, including all sub-parts thereof.

206. Defendants deny the allegations contained in Paragraph 206 of Plaintiff's Complaint.

207. Defendants deny the allegations contained in Paragraph 207 of Plaintiff's Complaint.

208. Defendants deny the allegations contained in Paragraph 208 of Plaintiff's Complaint.

PRAYER FOR RELIEF

Furthermore, responding to the unnumbered Paragraph, including sub-parts, following the heading "PRAYER FOR RELIEF" and beginning "WHEREFORE," Defendants deny the allegations contained in such Paragraph and all sub-parts thereof.

Defendants further deny each and every allegation not specifically admitted herein.

DEFENSES

Defendants allege as affirmative defenses the following:

1. Plaintiff's Complaint filed herein fails to state a claim or claims upon which relief can be granted under Rule 12 of the Federal Rules of Civil Procedure.

2. The sole proximate cause of Plaintiff's damages, if any were sustained, was the negligence of a person or persons or entity for whose acts or omissions Defendants were and are in no way liable.

3. Plaintiff's claims are barred, in whole or in part, by the applicable statutes of limitations and/or statute of repose.

4. If Plaintiff has been damaged, which Defendants deny, any recovery by Plaintiff is barred to the extent Plaintiff voluntarily exposed himself to a known risk and/or failed to mitigate his alleged damages. To the extent Plaintiff has failed to mitigate his alleged

1 damages, any recovery shall not include alleged damages that could have been avoided by
2 reasonable care and diligence.

3 5. If Plaintiff has been damaged, which Defendants deny, such damages were
4 caused by the negligence or fault of Plaintiff.

5 6. If Plaintiff has been damaged, which Defendants deny, such damages were
6 caused by the negligence or fault of persons and/or entities for whose conduct Defendants are
7 not legally responsible.

8 7. The conduct of Defendants and the subject product at all times conformed to
9 the Federal Food, Drug and Cosmetics Act, 21 U.S.C. § 301, *et seq.*, and other pertinent
10 federal statutes and regulations. Accordingly, Plaintiff's claims are barred, in whole or in
11 part, under the doctrine of federal preemption, and granting the relief requested would
12 impermissibly infringe upon and conflict with federal laws, regulations, and policies in
13 violation of the Supremacy Clause of the United States Constitution.

14 8. If Plaintiff has been damaged, which Defendants deny, such damages were
15 caused by unforeseeable, independent, intervening, and/or superseding events for which
16 Defendants are not legally responsible.

17 9. There was no defect in the product at issue with the result that Plaintiff is not
18 entitled to recover against Defendants in this cause.

19 10. If there were any defect in the products – and Defendants deny that there were
20 any defects – nevertheless, there was no causal connection between any alleged defect and
21 the product on the one hand and any damage to Plaintiff on the other with the result that
22 Plaintiff is not entitled to recover against Defendants in this cause.

23 11. Plaintiff's injuries, losses or damages, if any, were caused by or contributed to
24 by other persons or entities that are severally liable for all or part of Plaintiff's alleged
25 injuries, losses or damages. If Defendants are held liable to Plaintiff, which liability is
26 specifically denied, Defendants are entitled to contribution, set-off, and/or indemnification,
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1 either in whole or in part, from all persons or entities whose negligence or fault proximately
2 caused or contributed to cause Plaintiff's alleged damages.

3 12. Plaintiff's claims are barred to the extent that the injuries alleged in the
4 Plaintiff's Complaint were caused by the abuse, misuse, abnormal use, or use of the product
5 at issue in a manner not intended by Defendants and over which Defendants had no control.

6 13. Plaintiff's claims are barred to the extent that the injuries alleged in the
7 Plaintiff's Complaint were caused by a substantial change in the product after leaving the
8 possession, custody, and control of Defendants.

9 14. Plaintiff's breach of warranty claims are barred because: (1) Defendants did not
10 make any warranties, express or implied, to Plaintiff; (2) there was a lack of privity between
11 Defendants and Plaintiff; and (3) notice of an alleged breach was not given to the seller or
12 Defendants.

13 15. Plaintiff's claims for breach of implied warranty must fail because the product
14 was not used for its ordinary purpose.

15 16. Defendants neither had nor breached any alleged duty to warn with respect to
16 the product, with the result that Plaintiff is not entitled to recover in this cause.

17 17. Plaintiff's claims are barred by Defendants' dissemination of legally adequate
18 warnings and instructions to learned intermediaries.

19 18. At all relevant times, herein, Plaintiff's physicians were in the position of
20 sophisticated purchasers, fully knowledgeable and informed with respect to the risks and
21 benefits of the subject product.

22 19. If Plaintiff has been damaged, which Defendants deny, the actions of persons or
23 entities for whose conduct Defendants are not legally responsible and the independent
24 knowledge of these persons or entities of the risks inherent in the use of the product and other
25 independent causes, constitute an intervening and superseding cause of Plaintiff's alleged
26 damages.

1 20. To the extent that injuries and damages sustained by Plaintiff, as alleged in
2 Plaintiff's Complaint, were caused directly, solely, and proximately by sensitivities, medical
3 conditions, and idiosyncrasies peculiar to Plaintiff not found in the general public, they were
4 unknown, unknowable, or not reasonably foreseeable to Defendants.

5 21. Defendants believe, and upon that ground allege, that Plaintiff was advised of
6 the risks associated with the matters alleged in Plaintiff's Complaint and knowingly and
7 voluntarily assumed them. Pursuant to the doctrine of assumption of the risk, informed
8 consent, release, waiver, or comparative fault, this conduct bars in whole or in part the
9 damages that Plaintiff seeks to recover herein.

10 22. At all relevant times during which the device at issue was designed, developed,
11 manufactured, and sold, the device was reasonably safe and reasonably fit for its intended
12 use, was not defective or unreasonably dangerous, and was accompanied by proper warnings,
13 information, and instructions, all pursuant to generally recognized prevailing industry
14 standards and state-of-the-art in existence at the time.

15 23. Plaintiff's claims are barred because Plaintiff suffered no injury or damages as a
16 result of the alleged conduct and do not have any right, standing, or competency to maintain
17 claims for damages or other relief.

18 24. Plaintiff's claims are barred, in whole or in part, by the doctrines of waiver,
19 estoppel, and/or laches.

20 25. If Plaintiff suffered any damages or injuries, which is denied, Defendants state
21 that Plaintiff's recovery is barred, in whole or in part, or subject to reduction, under the
22 doctrines of contributory and/or comparative negligence.

23 26. In the further alternative, and only in the event that it is determined that
24 Plaintiff is entitled to recover against Defendants, recovery should be reduced in proportion to
25 the degree or percentage of negligence, fault or exposure to products attributable to Plaintiff,
26 any other defendants, third-party defendants, or other persons, including any party immune
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1 because bankruptcy renders them immune from further litigation, as well as any party, co-
2 defendant, or non-parties with whom Plaintiff has settled or may settle in the future.

3 27. Should Defendants be held liable to Plaintiff, which liability is specifically
4 denied, Defendants would be entitled to a setoff for the total of all amounts paid to Plaintiff
5 from all collateral sources.

6 28. Plaintiff's claims may be barred, in whole or in part, from seeking recovery
7 against Defendants pursuant to the doctrines of res judicata, collateral estoppel, release of
8 claims, and the prohibition on double recovery for the same injury.

9 29. The injuries and damages allegedly sustained by Plaintiff may be due to the
10 operation of nature or idiosyncratic reaction(s) and/or pre-existing condition(s) in Plaintiff
11 over which Defendants had no control.

12 30. The conduct of Defendants and all activities with respect to the subject product
13 have been and are under the supervision of the Federal Food and Drug Administration
14 ("FDA"). Accordingly, this action, including any claims for monetary and/or injunctive relief,
15 is barred by the doctrine of primary jurisdiction and exhaustion of administrative remedies.

16 31. Defendants assert any and all defenses, claims, credits, offsets, or remedies
17 provided by the Restatements (Second and Third) of Torts and reserve the right to amend
18 their Answer to file such further pleadings as are necessary to preserve and assert such
19 defenses, claims, credits, offsets, or remedies.

20 32. The device at issue complied with any applicable product safety statute or
21 administrative regulation, and therefore Plaintiff's defective design and warnings-based
22 claims are barred under the Restatement (Third) of Torts: Products Liability § 4, *et seq.* and
23 comments thereto.

24 33. Plaintiff cannot show that any reasonable alternative design would have
25 rendered the inferior vena cava filter device as alleged in Plaintiff's Complaint to be safer
26 overall under the Restatement (Third) of Product Liability § 2, cmt. f, nor could Defendants
27 have known of any alternative design that may be identified by Plaintiff.
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1 34. The device at issue was not sold in a defective condition unreasonably
2 dangerous to the user or consumer, and therefore Plaintiff's claims are barred under the
3 Restatement (Second) of Torts: Products Liability § 402A and comments thereto, and
4 comparable provisions of the Restatement (Third) of Torts (Products Liability).

5 35. At all relevant times during which the device at issue was designed, developed,
6 manufactured, and sold, the device was reasonably safe and reasonably fit for its intended
7 use, was not defective or unreasonably dangerous, and was accompanied by proper warnings,
8 information, and instructions, all pursuant to generally recognized prevailing industry
9 standards and state-of-the-art in existence at the time.

10 36. Defendants specifically plead all affirmative defenses under the Uniform
11 Commercial Code ("UCC") now existing or which may arise in the future, including those
12 defenses provided by UCC §§ 2-607 and 2-709.

13 37. Plaintiff's alleged damages, if any, should be apportioned among all parties at
14 fault, and any non-parties at fault, pursuant to the Uniform Contribution Among Tortfeasors
15 Act.

16 38. No act or omission of Defendants was malicious, willful, wanton, reckless, or
17 grossly negligent, and, therefore, any award of punitive damages is barred.

18 39. To the extent the claims asserted in Plaintiff's Complaint are based on a theory
19 providing for liability without proof of defect and proof of causation, the claims violate
20 Defendants' rights under the Constitution of the United States and analogous provisions of
21 the New York Constitution.

22 40. To the extent Plaintiff seeks punitive damages, Defendants specifically
23 incorporate by reference any and all standards of limitations regarding the determination
24 and/or enforceability of punitive damages awards that arose in the decisions of *BMW of*
25 *No. America v. Gore*, 517 U.S. 559 (1996); *Cooper Industries, Inc. v. Leatherman Tool*
26 *Group, Inc.*, 532 U.S. 424 (2001); *State Farm Mut. Auto Ins. Co. v. Campbell*, 123 S. Ct.
27 1513 (2003); and *Exxon Shipping Co. v. Baker*, No. 07-219, 2008 U.S. LEXIS 5263 (U.S.
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1 June 25, 2008) and their progeny as well as other similar cases under both federal and state
2 law.

3 41. Any of Plaintiff's claims for punitive or exemplary damages violate, and are
4 therefore barred by, the Fourth, Fifth, Sixth, Eighth and Fourteenth Amendments to the
5 Constitution of the United States of America, and similar provisions of the New York
6 Constitution, on grounds including the following:

- 7 (a) it is a violation of the Due Process and Equal Protection Clauses of the
8 Fourteenth Amendment of the United States Constitution to impose punitive
9 damages, which are penal in nature, against a civil defendant upon the plaintiffs
10 satisfying a burden of proof which is less than the "beyond a reasonable doubt"
11 burden of proof required in criminal cases;
- 12 (b) the procedures pursuant to which punitive damages are awarded may result in
13 the award of joint and several judgments against multiple defendants for
14 different alleged acts of wrongdoing, which infringes upon the Due Process and
15 Equal Protection Clauses of the Fourteenth Amendment of the United States
16 Constitution;
- 17 (c) the procedures to which punitive damages are awarded fail to provide a
18 reasonable limit on the amount of the award against Defendants, which thereby
19 violates the Due Process Clause of the Fourteenth Amendment of the United
20 States Constitution;
- 21 (d) the procedures pursuant to which punitive damages are awarded fail to provide
22 specific standards for the amount of the award of punitive damages which
23 thereby violates the Due Process Clause of the Fourteenth Amendment of the
24 United States Constitution;
- 25 (e) the procedures pursuant to which punitive damages are awarded result in the
26 imposition of different penalties for the same or similar acts, and thus violate
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the Equal Protection Clause of the Fourteenth Amendment of the United States Constitution;

(f) the procedures pursuant to which punitive damages are awarded permit the imposition of punitive damages in excess of the maximum criminal fine for the same or similar conduct, which thereby infringes upon the Due Process Clause of the Fifth and Fourteenth Amendments and the Equal Protection Clause of the Fourteenth Amendment of the United States Constitution;

(g) the procedures pursuant to which punitive damages are awarded permit the imposition of excessive fines in violation of the Eighth Amendment of the United States Constitution;

(h) the award of punitive damages to the plaintiff in this action would constitute a deprivation of property without due process of law; and

(i) the procedures pursuant to which punitive damages are awarded permit the imposition of an excessive fine and penalty.

42. Defendants expressly reserve the right to raise as an affirmative defense that Plaintiff has failed to join all parties necessary for a just adjudication of this action, should discovery reveal the existence of facts to support such defense.

43. Defendants reserve the right to raise such other affirmative defenses as may be available or apparent during discovery or as may be raised or asserted by other defendants in this case. Defendants have not knowingly or intentionally waived any applicable affirmative defense. If it appears that any affirmative defense is or may be applicable after Defendants have had the opportunity to conduct reasonable discovery in this matter, Defendants will assert such affirmative defense in accordance with the Federal Rules of Civil Procedure.

REQUEST FOR JURY TRIAL

Defendants C. R. Bard, Inc. and Bard Peripheral Vascular, Inc. demand a trial by jury on all issues appropriate for jury determination.

1 **WHEREFORE**, Defendants aver that Plaintiff is not entitled to the relief demanded in
2 the Plaintiff's Complaint, and these Defendants, having fully answered, pray that this action
3 against them be dismissed and that they be awarded their costs in defending this action and
4 that they be granted such other and further relief as the Court deems just and appropriate.

5 This 5th day of February, 2016.

6
7 s/Richard B. North, Jr.

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28 **Attorney for Defendants C. R. Bard, Inc. and
Bard Peripheral Vascular, Inc.**

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on February 5, 2016, I electronically filed the foregoing with the Clerk of the Court by using the CM/ECF system which will send notification of such filing to all counsel of record.

s/Richard B. North, Jr.
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